

Docket Number 23578-0010

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re the Application of )  
ARTHUR E UBER III, et al. ) Group Art Unit: 3737  
Application No.: 09/545,582 ) Examiner: Ruth Smith  
Filed: April 7, 2000 ) Confirmation No.: Unknown  
For: PATIENT INFUSION SYSTEM )  
FOR USE WITH MRI )

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Fifth Supplemental Information Disclosure Statement (“IDS”) is being filed to comply with Manual of Patent Examining Procedures (“M.P.E.P.”) § 2001.06(c) and provide the Office with litigation-related documents and the identification of references cited therein by the parties to the litigation entitled “Medrad, Inc. v. Tyco Healthcare Group LP, Mallinckrodt, Inc., Liebel-Flarsheim Co., and Nemoto Kyorindo Co., Ltd.” A portion of this case is pending before the United States District Court for the Western District of Pennsylvania and bears Docket No. 01-1997-GLL and a portion is pending before the United States Court of Appeals for the Federal Circuit and bears Docket No. 06-1082. The litigation concerns the accused infringement by Tyco Healthcare Group LP, Mallinckrodt, Inc., Liebel-Flarsheim Co., and Nemoto Kyorindo Co., Ltd. of United States Patent No. Re. 37,602 (“the ‘602 Patent”). (Hereinafter, the case will be referred to as “the ‘602 litigation”).

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Date: January 24, 2006

As discussed in the Supplemental Information Disclosure Statement filed on September 30, 2002, so that the Office may more readily understand the documents listed hereby and their relevance to this application, the Applicants respectfully point out that the '602 Patent is a reissue patent of United States Patent No. Re. 36,648 ("the '648 patent"). The '648 patent is a reissue of United States Patent No. 5,494,036 ("the '036 patent"). The '036 patent issued on February 27, 1996. The '648 patent issued on April 11, 2000. The '602 Patent issued on March 26, 2002. As a result, the '602 patent is related to the instant patent application.

## I. INTRODUCTION

In the '602 litigation, Medrad, Inc. ("Medrad") alleged that Tyco Healthcare Group LP, Mallinckrodt, Inc., Liebel-Flarsheim Co., and Nemoto Kyorindo Co., Ltd. ("defendants") have infringed several claims of the '602 Patent by making, using, selling and/or offering for sale the Optistar injector. In response, defendants denied Medrad's allegations and further alleged that the '602 Patent was invalid on several bases and unenforceable due to Medrad's inequitable conduct. The Applicants have attached an overview of the '602 litigation and other related litigation as Exhibit A hereto to assist the Examiner in understanding the background of the litigation. Also, the parties' pretrial statements, which were prepared in anticipation of trial in the '602 litigation, are listed as Cite Nos. AG (Medrad's pretrial statement) and AK (defendants' pretrial statement) on the PTO-1449 appended hereto and have been submitted with this IDS.<sup>1</sup>

In the '602 litigation, the parties filed numerous documents with the court and served numerous documents on each other to support their positions and to rebut the allegations

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<sup>1</sup> At the time of their filing, both pretrial statements were designated "Confidential" pursuant to the protective order in the '602 litigation. Medrad has waived confidentiality of its relevant business information included in its pretrial statement. Moreover, the Applicants have redacted any confidential information of defendants contained in Medrad's pretrial statement. As for Defendants' Pretrial Statement, the Applicants have submitted the copy that was filed by defendants' with the court on the public court filing system in the '602 litigation.

presented by the opposing party. To comply with the MPEP § 2001.06(c), the Applicants have listed litigation documents filed and served by the parties to the litigation that related to the validity of the '602 patent or to defendants' inequitable conduct allegations on the PTO-1449 appended hereto. The Applicants have also submitted many of those documents along with this information disclosure statement ("IDS").<sup>2</sup> The Applicants have summarized a group of the documents below.

The defendants cited a wide variety of references in this litigation in connection with their positions. One litigation document in particular in which defendants cited a wide variety of references was Defendants' Notice Under 35 U.S.C. § 282, filed on September 2, 2005 (attached hereto as Exhibit B and listed as Cite No. AJ on the PTO-1449 appended hereto). Many of the references cited by the defendants have previously been submitted to the Office in this application, and only those references not previously submitted are listed on the attached PTO-1449.

The Applicants respectfully submit that the materiality of the litigation documents and the references identified therein is based on the assertions by the defendants in the '602 litigation. The Applicants are submitting the identification of the litigation documents and the references cited therein because they are being asserted against related patents owned by Medrad, the assignee of the instant application. By supplying the identification of the litigation

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<sup>2</sup> Many documents listed on the PTO-1449 appended hereto were designated "Confidential" pursuant to the protective order in the '602 litigation. For the "Confidential" documents that were filed and/or served on behalf of Medrad, Medrad has waived confidentiality of its relevant business information and the Applicants have redacted all confidential information of defendants contained therein. These documents have been submitted along with this IDS. For the "Confidential" documents filed and/or served by defendants in the '602 litigation, the Applicants have listed them on the PTO-1449 appended hereto under the section entitled "The Following Documents Include Confidential Information Pursuant to Protective Order and Have Not Been Submitted." These documents are not submitted along with this IDS.

documents and the references cited therein, the Applicants are making no assertion, expressly or implicitly, that the claims of the instant application are either anticipated or rendered obvious by those references.

## **II. OVERVIEW OF PARTIES' LITIGATION DOCUMENTS**

In the '602 litigation, the parties retained various experts to testify at trial. Each of these experts provided an independent expert opinion regarding one or more of the issues in the case in the form of an expert report. The following list identifies the experts for each party that provided an opinion relating to the validity of the '602 Patent or defendants' inequitable conduct allegations, and the subject matter to which the experts opined:

### **1. Experts Retained by Medrad, Inc.**

#### **a. Dr. Bruce R. Rosen, M.D., Ph.D.**

Dr. Rosen, Medrad's primary expert witness, is currently the Director of the Massachusetts General Hospital NMR Center, and a Professor of Radiology at the Harvard Medical School. Dr. Rosen has an undergraduate degree in Astronomy and Astrophysics from Harvard University, a master's degree in physics from Massachusetts Institute of Technology ("MIT"), a medical degree from Hahnemann Medical College in Philadelphia and a Ph.D. in Medical Physics from MIT. Dr. Rosen provided his opinion regarding Medrad's infringement allegations and defendants' anticipation and obviousness allegations.

#### **b. Philip R. Hall**

Mr. Hall is currently the President of Ross Design Services. Mr. Hall has a Bachelor of Science degree in both Electrical Engineering and Mechanical Engineering from Pennsylvania

State University. Mr. Hall provided his opinion regarding Medrad's infringement allegations and defendants' anticipation and obviousness allegations.

c. Paul A. Beck

Mr. Beck is an attorney that has been admitted to practice before the PTO for over 40 years. He has a Bachelor of Science degree in Electrical Engineering from Carnegie Mellon University. Mr. Beck has provided his opinion regarding the practice of prosecuting patents before the United States Patent and Trademark Office ("PTO") in general and the practice of prosecuting reissue patents in particular. Mr. Beck has also provided his opinion regarding defendants' allegations of Medrad's inequitable conduct in the prosecution of the '602 Patent.

**2. Experts Retained by Tyco Healthcare Group LP *et al.***

a. Robert A. Bell, Ph.D.

Dr. Bell, defendants' primary expert witness, is currently President of R.A. Bell and Associates. Dr. Bell has undergraduate and graduate degrees in Chemistry from California Institute of Technology ("Caltech"), a master's degree in Chemistry from Princeton University and a Ph.D. from Princeton as well. Dr. Bell was a Post-Doctoral Research Fellow at Caltech. Dr. Bell provided his expert opinion regarding the defendants' invalidity allegations and responded to Medrad's infringement allegations.

b. Richard D. Grauer

Mr. Grauer is an attorney at the law firm of Rader, Fishman & Grauer, PLLC. Previously, he was a patent examiner at the PTO. Mr. Grauer has a Bachelor of Science degree in Mechanical Engineering from the University of Michigan, a Master's degree in Automotive Engineering from the Chrysler Institute of Engineering and a Juris Doctor from George

Washington University. Mr. Grauer provided his opinion regarding defendants' allegations of Medrad's inequitable conduct in prosecuting the '602 Patent before the PTO.

c. Steven Wolff, M.D., Ph.D.

Dr. Wolff is currently the Director of Cardiovascular MRI & CT at the Cardiovascular Research Foundation, Chief of Cardiovascular MRI at Lenox Hill Hospital, Director of Advanced Cardiovascular Imaging at Advanced Cardiovascular Imaging, and President of Radiology Consultant. He received his Bachelor of Science degree from Yale University, and his Medical Degree and Ph.D. from Duke University. Dr. Wolff provided his opinion regarding defendants' allegations that certain of the asserted claims of the '602 Patent were invalid because the *at least two syringe* limitation was known in the prior art and would have been obvious to a person having ordinary skill in the art at the time the patent application was filed.

d. William L. Schultz, Ph.D., P.E.

Mr. Schultz is a Registered Professional Engineer and teaches several electrical engineering related courses, including P.E. examination refresher courses. He received a Bachelor of Science degree in electrical engineering, a Master's degree in instrumentation engineering, and a Ph.D. in electrical engineering from Case Western Reserve University. Mr. Schultz provided his opinion regarding defendants' allegations that the claims of the '602 Patent were invalid and Medrad's infringement allegations.

e. Bruce A. Eisenstein, Ph.D., P.E.

Mr. Eisenstein is a Professor of Electrical and Computer Engineering at Drexel University. He has a Bachelor of Science degree in electrical engineering from Massachusetts Institute of Technology, a Master of Science degree in electrical engineering from Drexel University, and a Ph.D. in electrical engineering from University of Pennsylvania. Mr.

Eisenstein was also a Summer Faculty Fellow in the Department of Aeronautics and Astronautics at Stanford University and a Research Fellow in electrical engineering at Princeton University. Mr. Eisenstein provided his opinion regarding defendants' invalidity allegations and Medrad's infringement allegations.

f. Karen Becker, Ph.D.

Ms. Becker is President of Becker & Associates Consulting, Inc. She has a Bachelor of Science degree in biological chemistry from the University of Maryland and a Ph.D. in pharmacology from the University of North Carolina School of Medicine. Ms. Becker provided her opinion regarding defendants' invalidity allegations. Specifically, Ms. Becker concluded that Medrad's 510(K) file for Medrad's MRI Injection System, file number K873173, including the 1987 Magnetic Resonance Injector Operation Manual, was publicly available before the critical date for the '602 Patent.

g. Robert Lee, Ph.D.

Mr. Lee is a Professor at the Ohio State University. Mr. Lee has a Bachelor of Science degree in electrical engineering from Lehigh University and a Master of Science degree and a Ph.D. from the University of Arizona. Mr. Lee provided his opinion regarding defendants' invalidity allegations and Medrad's infringement allegations.

**3. Summaries of Expert Reports**

As discussed above, in the '602 litigation, the parties submitted several expert reports in support of their validity, invalidity, and inequitable conduct positions. The Applicants provide a brief summary of the contents of these reports below in reverse chronological order of their submission date:

- a. Revised Supplemental Rebuttal Expert Report of Bruce Rosen, filed on behalf of Medrad, Inc., submitted on 08/19/05 (Confidential Pursuant to Protective Order Attorney's Eyes Only)

In this supplemental rebuttal report, Dr. Rosen concluded that Medrad's prototype EM-1 MRI injector did not invalidate the claims of the '602 Patent. *See* Cite No. AH on the PTO-1449 appended hereto for Dr. Rosen's expert report.

- b. Use of EIA RS-422 Digital Signals in the Environment of and Operating NMR Imaging System by William Schultz, Ph.D, P.E. (Revised Report), filed on behalf of Tyco Healthcare Group LP *et al.*, submitted on 04/05/05

In his report, Dr. Schultz concluded that a cable transmitting RS-422 communication signal generates electromagnetic radiation that is subsequently minimized or reduced by electrostatic shielding and the combination of differential signaling and twisted pair cables. *See* Cite No. N on the PTO-1449 appended hereto for Dr. Schultz's expert report. Dr. Schultz further concluded that a person having ordinary skill in the art would have known of these characteristics of RS-422 at the time of Medrad's alleged invention. Finally, Dr. Schultz concluded that there are substantial differences between RS-422 and the link described in the '602 Patent.

- c. Supplemental Rebuttal Expert Report of Philip R. Hall, filed on behalf of Medrad, Inc., submitted on 03/26/05 (Confidential Pursuant to Protective Order Attorney's Eyes Only)

In this supplemental report, Mr. Hall concluded that it would not have been obvious to a person having ordinary skill in the art to use RS-422, the communication protocol used in the defendants' accused Optistar products, to reduce the emission of electromagnetic radiation during the operation of an MRI injector. *See* Cite No. M on the PTO-1449 appended hereto for Mr. Hall's expert report.

- d. Rebuttal Expert Report of Paul A. Beck, filed on behalf of Medrad, Inc., submitted on 03/16/05 (Attorneys' Eyes Only)

In his rebuttal report, Mr. Beck rebutted the opinions provided by defendants' experts Mr. Grauer and Ms. Becker. *See* Cite No. J on the PTO-1449 appended hereto for Mr. Beck's expert

report. In particular, Mr. Beck concluded that Medrad did not perform inequitable conduct during the prosecution of the '602 Patent or its predecessor patents before the PTO. Mr. Beck also concluded that a certain alleged prior art reference, Medrad's 1987 Magnetic Resonance Injector Operation Manual, did not qualify as prior art under 35 U.S.C. § 102.

- e. Rebuttal Expert Report of Philip R. Hall, filed on behalf of Medrad, Inc., submitted on 03/16/05 (Confidential Pursuant to Protective Order Attorney's Eyes Only)

In this report, Mr. Hall concluded that the RS-232 communication protocol could not transmit viable signals across the cable and filter used in defendants' accused Optistar products. *See* Cite No. L on the PTO-1449 appended hereto for Mr. Hall's expert report. Mr. Hall also concluded that transmitting such a signal without a filter generated unacceptable noise levels in the MRI environment.

- f. Rebuttal Expert Report of Dr. Bruce Rosen, filed on behalf of Medrad, Inc., submitted on 03/16/05 (Confidential – Attorneys Eyes Only)

Dr. Rosen, in his rebuttal report, concluded that the evidence provided by defendants' experts was insufficient to invalidate the '602 Patent. *See* Cite No. I on the PTO-1449 appended hereto for Dr. Rosen's expert report. The patents and publications on which Dr. Rosen based his validity opinion are listed (along with other references) on Defendants' Notice Under 35 U.S.C. § 282, which was filed on September 2, 2005.

- g. Report of Bruce A. Eisenstein, Ph.D., P.E., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, filed on behalf of Tyco Healthcare Group LP *et al.*, submitted on 03/16/05

In his report, Dr. Eisenstein concluded that RS-422 as a communication link in the MRI environment would have been obvious to a person skilled in the art before November 26, 1992 and that such a person would also have known that RS-422 used within an MRI environment

would create noise, but would simultaneously ameliorate any radio frequency interference. *See* Cite No. K on the PTO-1449 appended hereto for Dr. Eisenstein's expert report. Dr. Eisenstein also concluded that RS-422 and the communication link disclosed in the '602 Patent are substantially different.

h. Expert Report of Paul A. Beck, filed on behalf of Medrad, Inc., submitted on 02/14/05 (Attorneys' Eyes Only)

In his expert report, Mr. Beck provided his expert opinion on the practices and procedures of prosecuting patents before the United States Patent & Trademark Office in general and the prosecution of the '602 Patent and its predecessor patents in particular. *See* Cite No. F on the PTO-1449 appended hereto for Mr. Beck's expert report.

i. Expert Report of Robert A. Bell, M.D. on behalf of Tyco, 02/14/05 (Portions of This Report Include Information that has been Designated Attorneys' Eyes Only Under the Protective Order)

In his report, Dr. Bell concluded that the '602 Patent is invalid in light of several pieces of alleged prior art. *See* Cite No. BB on the PTO-1449 appended hereto for Dr. Bell's expert report. The patents and publications on which Dr. Bell based his invalidity opinion are listed (along with other references) on Defendants' Notice Under 35 U.S.C. § 282, which was filed on September 2, 2005. Dr. Bell also concluded that the asserted claims of the '602 Patent are not infringed by the defendants' accused products.

j. Report of Steven Wolff, M.D., Ph.D., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, filed on behalf of Tyco Healthcare Group LP *et al.*, submitted on 02/14/05

In his expert report, Dr. Wolff concluded that two-syringe injectors existed for use in other imaging modalities at the time of Medrad's invention and that it would have been obvious to those

having ordinary skill in the art to incorporate two-syringe injectors into the MRI context. *See Cite No. G* on the PTO-1449 appended hereto for Dr. Wolff's expert report.

- k. Report of Defendants' Expert Witness Richard D. Grauer Pursuant to Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, filed on behalf of Tyco Healthcare Group LP *et al.*, submitted on 02/14/05

In his report, Mr. Grauer concluded that material information was withheld from and/or misrepresented to the USPTO during the prosecution of the '602 Patent and its predecessors. *See Cite No. H* on the PTO-1449 appended hereto for Mr. Grauer's expert report. Mr. Grauer further concluded that there is an adequate basis for a finder of fact to conclude that the Applicants and/or their attorneys demonstrated a deceptive intent with regard to the withheld and misrepresented material information.

The Applicants have appended to Mr. Grauer's report a copy of the June 8, 2001 IDS that was submitted in the prosecution of the '602 Patent which is discussed by Mr. Grauer in connection with his opinion on inequitable conduct.

- l. Expert Report of Phillip R. Hall, on behalf of Medrad, Inc., submitted on 05/20/03 (Confidential Pursuant to Protective Order)

In his expert report, Mr. Hall concluded that Medrad's prototype EM-1 MRI injector did not invalidate the '602 Patent. *See Cite No. C* on the PTO-1449 appended hereto for Mr. Hall's expert report. The prototype injector on which Mr. Hall based his validity opinion is listed (along with other references) on Defendants' Notice Under 35 U.S.C. § 282, which was filed on September 2, 2005. Mr. Hall also concludes that the communication link in the defendants' accused products meets the "substantially non-reactive" limitation in several of the asserted claims of the '602 Patent, and therefore the accused products infringe.

- m. Report of Robert A. Bell, Ph.D., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, on behalf of Tyco, submitted on 05/20/03 (Portions of This

Report Include Information that has been Designated Attorneys' Eyes Only  
Under the Protective Order)

In his report, Dr. Bell concluded that the '602 Patent is invalid in light of several pieces of alleged prior art. *See* Cite No. BA on the PTO-1449 appended hereto for Dr. Bell's expert report. Dr. Bell also concluded that the asserted claims of the '602 Patent are not infringed by the defendants' accused Optistar products.

- n. Report of Robert Lee, Ph.D., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, on behalf of Tyco, submitted on 05/16/03 (Portions of This Report Include Information that has been Designated Attorneys' Eyes Only Under the Protective Order)

In this report, Dr. Lee opined that the use of shielded electrical cables in the MRI environment would be known by a person having ordinary skill in the art at the time that the application for the '602 Patent was filed. *See* Cite No. BA on the PTO-1449 appended hereto for Dr. Lee's expert report. Dr. Lee also concluded that the communication link in the defendants' accused product was substantially different than the link disclosed in the '602 Patent.

- o. Amended Report of Tyco expert Karen Becker, Ph.D., filed on behalf of Tyco Healthcare Group LP, *et al.*, submitted on 05/16/03

In her expert report, Dr. Becker concluded that a file containing information required by the United States Food and Drug Administration, including a copy of the 1987 Magnetic Resonance Injector Operation Manual, was publicly available more than one year prior to the filing of the application that resulted in the '602 Patent. *See* Cite No. AZ on the PTO-1449 appended hereto for Dr. Becker's expert report.

- p. Expert Report of Dr. Bruce R. Rosen, on behalf of Medrad, Inc., submitted on 05/13/03 (Confidential Pursuant to Protective Order)

In his expert report, Dr. Rosen concluded that the evidence provided by defendants was insufficient to invalidate the '602 Patent. *See* Cite No. A on the PTO-1449 appended hereto for Dr.

Rosen's expert report. The patents and publications on which Dr. Rosen based his validity opinion are listed (along with other references) on Defendants' Notice Under 35 U.S.C. § 282, which was filed on September 2, 2005. Dr. Rosen also concluded that the defendants' accused Optistar product infringed the asserted claims of the '602 Patent.

#### **4. Summary Judgment Motions**

The parties to the '602 litigation also filed several dispositive motions for summary judgment. Medrad filed four summary judgment motions: (1) Medrad's Motion for Summary Judgment of No Invalidity Based on Medrad's Grounds for Filing the Reissue Application that Resulted in the '602 Reissue Patent, (2) Medrad's Motion for Summary Judgment of No Invalidity of Claims 9, 33 and 38 Under 35 U.S.C. § 102 Based on Medrad's EM-1 Prototype Injector, (3) Medrad's Motion for Summary Judgment of No Invalidity Based on the Saini Article and the 1987 Magnetic Resonance Injector Operation Manual, and (4) Medrad's Motion for Summary Judgment of Infringement of Claim 37 Under 35 U.S.C. § 271(b).

The defendants filed five summary judgment motions: (1) Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Defective Reissue, (2) Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. § 112, (3) Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. §103, (4) Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. § 102(b), and (5) Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Prior Public Use. The briefing for the

summary judgment motions that related to defendants' invalidity allegations are summarized below.

### **5. Summaries of Summary Judgment Motions**

As discussed above, the parties to the '602 litigation filed several motions for summary judgment that related to the validity of the '602 Patent. These summary judgment motions and the briefing accompanying those motions are summarized below:

- a. Medrad's Motion for Summary Judgment of No Invalidity of Claims 9, 33 and 38 Under 35 U.S.C. § 102 Based on Medrad's EM-1 Prototype Injector and Memoranda in Support, filed on 04/25/05

In its briefing in support of this summary judgment motion, Medrad argued that the use of its EM-1 prototype injector did not invalidate the claims of the '602 Patent because the use was primarily for experimental purposes. *See Cite Nos. P* (Medrad's Motion and Memorandum in Support) and AF (Medrad's Reply) on the PTO-1449 appended hereto for Medrad's briefing on this Motion.

Moreover, Medrad also argued that the use of its EM-1 prototype injector did not invalidate the claims of the '602 Patent because it did not include each and every limitation of the asserted claims. In its brief in opposition to this motion, defendants alleged that Medrad's EM-1 prototype injector invalidated claims 9, 33 and 38 of the '602 patent because it included each and every limitation of those claims and it was used prior to the critical date. *See Cite No. BH* on the PTO-1449 appended hereto for defendants' briefing on this Motion. Defendants alleged that Medrad's use of the EM-1 prototype injector was not experimental, but rather was primarily for commercial purposes.

- b. Medrad's Motion for Summary Judgment of No Invalidity Based on the Saini Article and the 1987 Magnetic Resonance Injector Operation Manual, filed on 04/25/05

In its briefing in support of this motion, Medrad argued that neither an operator's manual for its EM-1 prototype injector, the 1987 Magnetic Resonance Injector Operation Manual, nor an article

authored by Saini *et al.* invalidated claim 25 of the ‘602 Patent because they did not include each and every element of that claim. *See* Cite Nos. Q and AE on the PTO-1449 appended hereto for Medrad’s briefing on this Motion. Medrad argued that both of these alleged prior art references failed to disclose an injector that had “two or more syringes each contacting, interlocking or meshing with at least one drive mechanism of the injector” as required by the court’s claim construction. In its opposition briefing, defendants argued that both of the references include such a limitation because both alleged prior art references describe injectors that have two or more syringes that have the ability to contact, interlock or mesh with the drive mechanism of the injector at separate times. *See* Cite No. BG on the PTO-1449 appended hereto for defendants’ briefing on this Motion.

c. Defendants’ Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 112, filed 04/25/05

In its briefing in support of this motion, defendants argued that the claims of Medrad’s ‘602 Patent are invalid because Medrad failed to disclose the best mode of practicing the invention as required under 35 U.S.C. § 112. *See* Cite Nos. S (Motion), BC (Memorandum In Support of Motion) and BJ (Reply) on the PTO-1449 appended hereto for defendants’ briefing on this issue. Specifically, defendants alleged that the inventors failed to disclose the best mode for the material choice for the “infusion apparatus,” the configuration of the “communication link” or “communication” or the characteristics of the battery or the battery charger of the inventions. Medrad, in its opposition brief, argued that the claims of the ‘602 Patent were not invalid for failure to comply with § 112. *See* Cite No. X on the PTO-1449 appended hereto for Medrad’s briefing on this issue. Medard argued that the inventors did not have a subjective best mode of practicing the “communication link” or “communication” of the inventions. Medrad also argued that an understanding of the materials and characteristics of the “infusion apparatus” and the battery and

battery charger of the inventions would have been routine to a person having ordinary skill in the art and therefore the best mode doctrine did not apply to those details.

- d. Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 103, filed on 04/25/05

Defendants alleged, in support of its motion, that the asserted claims of the '602 Patent were invalid under 35 U.S.C. § 103 because they would have been obvious to a person having ordinary skill in the art at the time they were filed. *See* Cite Nos. T (Motion), BD (Memorandum In Support of Motion) and BL (Reply) on the PTO-1449 appended hereto for defendants' briefing on this Motion. Defendants primarily relied on Medrad's EM-1 prototype MRI injector, the 1987 Magnetic Resonance Injector Operation Manual and the disclosure of the article authored by Saini *et al.* to support its allegations that the claims of the '602 Patent would have been obvious. Medrad argued, in opposition to defendants' motion, that some of the references were not prior art under 35 U.S.C. § 102, and, moreover, there was no motivation or suggestion to combine references. *See* Cite No. Z on the PTO-1449 appended hereto for Medrad's briefing on this Motion. Medrad also argued that the asserted claims would not have been obvious to a person having ordinary skill in the art and that the secondary considerations rebut any showing of obviousness.

- e. Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 102(b) for being "On Sale", filed on 04/25/05

Defendants alleged, in support of its motion, that the asserted claims of the '602 patent were invalid under 35 U.S.C. § 102(b) because inventions claimed were offered for sale and/or sold more than one year prior to the filing date of the application that led to the '602 Patent. *See* Cite Nos. U, BE and BK on the PTO-1449 appended hereto for the defendants' briefing on this Motion. Specifically, defendants alleged that the interactions between Medrad and a third-party resulted in an

offer for sale of the claimed invention prior to the critical date. Medrad argued, in opposition to defendants' motion, that no sale or offer for sale took place more than one year prior to the critical date. *See* Cite No. Y on the PTO-1449 appended hereto for the Medrad's briefing on this Motion.

- f. Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE. 37,602 Based on Prior Public Use, filed on 04/25/05

The briefing on this motion is similar to the briefing on Medrad's Motion for Summary Judgment of No Invalidity of Claims 3, 33 and 38 Under 35 U.S.C. § 102 Based on Medrad's EM-1 Prototype Injector and Memoranda in Support, filed on 04/25/05 (*see ¶ a above*). *See* Cite Nos. V, BF and BI on the PTO-1449 appended hereto for the defendants' briefing on this Motion; Cite No. W on the PTO-1449 appended hereto for the Medrad's briefing on this Motion.

- g. Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Defective Reissue, filed on 04/25/05

In its briefing in support of its motion, defendants alleged that Medrad's '602 Patent was invalid because Medrad was not correcting one of the four statutorily identified errors in 35 U.S.C. § 251 when it filed the application that resulted in the '602 Patent. *See* Cite Nos. R and AC on the PTO-1449 appended hereto for defendants' briefing on this Motion. Specifically, defendants argued that Medrad's failure to file supplemental declarations in the prosecution of the '602 Patent's predecessor was not the type of error that was correctable under § 251. In response, Medrad argued that its failure to file supplemental declarations is correctable under § 251 and therefore the '602 Patent is not invalid. *See* Cite No. AA on the PTO-1449 appended hereto for Medrad's briefing on this Motion.

h. Medrad's Motion for Summary Judgment of No Invalidity Based on Medrad's Grounds for Filing the Reissue Application that Resulted in the '602 Reissue Patent, filed on 04/25/05

The briefing on this motion is similar to the briefing on Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Defective Reissue, filed on 04/25/05 (*see ¶ g above*). *See* Cite Nos. O and AD on the PTO-1449 appended hereto for Medrad's briefing on this Motion; Cite No. AB on the PTO-1449 appended hereto for defendants' briefing on this Motion.

## 6. Other Litigation Documents

a. District Court Order Granting Defendants' Motion for Summary Judgment

In the '602 litigation, the District Court granted the defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Defective Reissue. *See* Memorandum and Order granting Motion for Summary Judgment and denying Motion for Summary Judgment, entered on 10/12/05, attached hereto as Exhibit 4 to Exhibit A.<sup>3</sup> The District Court found that the '602 Patent was invalid because Medrad did not have a proper basis for filing the reissue application that resulted in the '602 Patent under 35 U.S.C. § 251.

b. District Court's July 16 and August 5, 2004 Memorandum Orders on Claim Construction

In the '602 litigation, the District Court entered two Memorandum Orders on claim construction. *See* District Court's July 16, 2004 Memorandum Order, Cite No. D on the PTO-1449 appended hereto; District Court's August 5, 2004 Memorandum Order, Cite No. E on the PTO-1449 appended hereto.

c. United States International Trade Commission Initial Determination

Prior to the '602 litigation, Medrad, Mallinckrodt, Liebel-Flarsheim, and Nemoto Kyorindo were involved in litigation before the United States International Trade Commission (hereinafter referred to as the "ITC litigation") regarding the '602 Patent's predecessor, U.S. Patent No. Re. 36,648 ("the '648 Patent"). In the ITC litigation, the Administrative Law Judge ("ALJ") issued an initial determination that the '648 Patent was invalid. *See Initial Determination Granting Nemoto's Motion No. 434-6 For Summary Determination and Liebel's Motion No. 434-11 For Summary Determination And Finding The '648 Patent, The Sole Patent In Issue In This Investigation, Invalid*, attached hereto as Exhibit 1 to Exhibit A. The ALJ in the ITC litigation found that Medrad's failure to file a supplemental oath or declaration before allowance of the claims in the reissue application rendered the '648 Patent invalid. *See id.* at p. 24.

**III. CONCLUSION**

Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. It is respectfully requested that this information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent issuing therefrom.

The Applicants respectfully submit that the references listed on the attached PTO-1449 under the section entitled "The Following Documents Include Confidential Information Pursuant to

<sup>3</sup> The District Court entered a Corrected Order on November 4, 2005. This Corrected Order is attached hereto as Exhibit 5 to Exhibit A.

Protective Order and Have Not Been Submitted" are subject to the Protective Order in the '602 litigation. Therefore, the Applicants are prohibited from submitting copies herewith. By listing the documents on the attached PTO-1449, the Applicants believe that they have complied fully with 37 CFR § 1.56 and have not violated any Court Orders in doing so. Should the defendants give Medrad, the Assignee of the above-captioned application, permission to submit the references at a future date, before the issuance of this application as a Reissue Patent, the Applicants will endeavor to supply copies to the Office so that they may be considered.

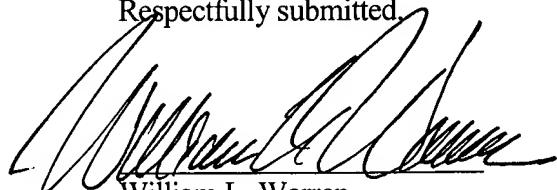
Pursuant to 37 CFR § 1.56, the attention of the Patent and Trademark Office is hereby directed to the identification of the references listed on the attached PTO-1449 under the section entitled "The Following Documents Include Confidential Information Pursuant to Protective Order and Have Not Been Submitted." It is respectfully requested that this information be expressly considered during the prosecution of this application. Since copies of the references are not provided herewith, for the reason set forth above, the Applicants respectfully request that this Fifth Supplemental IDS be placed in the file for the above-captioned patent application, to become a permanent part of the record.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.

Please charge Deposit Account 19-5029 in the amount of \$180.00 in payment of the fee under 37 CFR § 1.17(p). Please credit or debit Deposit Account 19-5029 as needed to ensure consideration of the disclosed information. Two duplicated copies of this paper are attached.

Consideration of the foregoing and enclosures plus the return of a copy of the enclosed Form PTO-1449 with the Examiner's initials in the left column per MPEP 609 are earnestly solicited along with an early action on the merits.

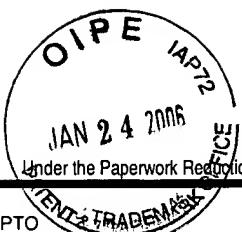
Respectfully submitted,



William L. Warren  
Registration Number 36714

Dated: January 24, 2006

SUTHERLAND ASBILL & BRENNAN  
999 Peachtree Street, NE  
Atlanta, Georgia 30309-3996  
404.853.8000  
SAB Docket No. 23578-0010



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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				Complete if Known	
Sheet	1	of	6	Application Number	09/545,582
				Filing Date	April 7, 2000
				First Named Inventor	Arthur E Uber III
				Art Unit	3737
				Examiner Name	Ruth Smith
				Attorney Docket Number	23578-0010

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the articles (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A	Report of Dr. Bruce R. Rosen, filed on behalf of Medrad, Inc., submitted on 05/13/03 (Confidential Pursuant to Protective Order)	
	B	Amended report of Tyco expert Karen Becker, Ph.D., filed on behalf of Tyco Healthcare Group LP <i>et al.</i> , submitted on 05/16/03 and exhibits thereto, including Exhibit F, DIOGENES, The 510(K) Register, 1990 ed., covering May 1976-Dec. 1989, cover page and page 1-301.	
	C	Report of Medrad expert Phillip R. Hall, filed on behalf of Medrad, Inc., submitted on 05/20/03 (Confidential Pursuant to Protective Order)	
	D	Memorandum Order, entered on July 16, 2004,	
	E	Memorandum Order, entered on August 5, 2004.	
	F	Expert Report of Paul A. Beck, filed on behalf of Medrad, Inc., submitted on 02/14/05 (Attorneys' Eyes Only)	
	G	Report of Steven Wolff, M.D., Ph.D., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, filed on behalf of Tyco Healthcare Group LP <i>et al.</i> , submitted on 02/14/05	
	H	Report of Defendants' Expert Witness Richard D. Grauer Pursuant to Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, filed on behalf of Tyco Healthcare Group LP <i>et al.</i> , submitted on 02/14/05 -- Applicants appended to this expert report the June 8, 2001 IDS filed with the USPTO in the prosecution of U.S. Patent No. Re. 37,602, discussed in Mr. Grauer's report.	
	I	Rebuttal Expert Report of Bruce R. Rosen, filed on behalf of Medrad, Inc., submitted on 03/16/05 (Confidential – Attorneys Eyes Only)	
	J	Rebuttal Expert Report of Paul A. Beck, filed on behalf of Medrad, Inc., submitted on 03/16/05 and exhibits thereto, including Exhibit 2, various correspondence between parties' counsel after the conclusion of the ITC investigation regarding the handling of discovery documents in light of the protective order in place (Attorneys' Eyes Only)	
	K	Report of Bruce A. Eisenstein, Ph.D., P.E., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, filed on behalf of Tyco Healthcare Group LP <i>et al.</i> , submitted on 03/16/05	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.

<sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-766-9199) and select option 2.

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Substitute for form 1449/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				Application Number	09/545,582
Sheet	2	of	6	Filing Date	April 7, 2000
				First Named Inventor	Arthur E Uber III
				Art Unit	3737
				Examiner Name	Ruth Smith
				Attorney Docket Number	23578-0010

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the articles (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	L	Rebuttal Expert Report of Philip R. Hall, filed on behalf of Medrad, Inc., submitted on 03/16/05 (Confidential Pursuant to Protective Order Attorney's Eyes Only)			
	M	Supplemental Rebuttal Expert Report of Philip R. Hall, filed on behalf of Medrad, Inc., submitted on 03/26/05 (Confidential Pursuant to Protective Order Attorney's Eyes Only)			
	N	Revised Report of William L. Schultz: Use of EIA RS-422 Digital Signals in the Environment of and Operating NMR Imaging System by William L. Schultz, Ph.D., P.E., Principal, filed on behalf of Tyco Healthcare Group LP <i>et al.</i> , submitted on 04/05/05			
	O	Medrad's Motion for Summary Judgment of No Invalidity Based on Medrad's Grounds for Filing the Reissue Application that Resulted in the '602 Reissue Patent and Memoranda in Support, submitted on 04/25/05			
	P	Medrad's Motion for Summary Judgment of No Invalidity of Claims 9, 33 and 38 Under 35 U.S.C. § 102 Based on Medrad's EM-1 Prototype Injector and Memoranda in Support, submitted on 04/25/05 (Filed Under Seal)			
	Q	Medrad's Motion for Summary Judgment of No Invalidity Based on the Saini Article and the 1987 Magnetic Resonance Injector Operation Manual and Memoranda in Support, submitted on 04/25/05 (Filed Under Seal)			
	R	Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Defective Reissue and Memoranda in Support, submitted on 04/25/05			
	S	Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. § 112, ¶ 1, submitted on 04/25/05			
	T	Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. § 103, submitted on 04/25/05			
	U	Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. § 102(b) for being "On Sale", submitted on 04/25/05			
	V	Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Prior Public Use, submitted on 04/25/05			
	W	Medrad's Opposition to Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Prior Public Use, submitted on 05/27/05 (Filed Under Seal)			
	X	Medrad's Opposition to Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. § 112, ¶ 1, submitted on 05/27/05 (Filed Under Seal)			

Examiner Signature		Date Considered	
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<p>Substitute for form 1449/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)</p>				Complete if Known	
				Application Number	09/545,582
				Filing Date	April 7, 2000
				First Named Inventor	Arthur E Uber III
				Art Unit	3737
Examiner Name	Ruth Smith				
Sheet	3	of	6	Attorney Docket Number	23578-0010

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the articles (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	Y	Medrad's Opposition to Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. § 102 (b) for Being "On Sale," submitted on 05/27/05 (Filed Under Seal)			
	Z	Medrad's Opposition to Defendants' Memorandum for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE 37,602 Under 35 U.S.C. § 103, submitted on 05/27/05 (Filed Under Seal)			
	AA	Medrad's Opposition to Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Defective Reissue, submitted on 05/27/05			
	AB	Defendants' Opposition to Medrad's Motion for Summary Judgment of No Invalidity Based on Medrad's Grounds for Filing the Reissue Application that Resulted in the '602 Re-Reissue Patent, submitted on 05/27/05			
	AC	Defendants' Reply in Support of Their Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Defective Reissue, submitted on 06/13/05			
	AD	Medrad's Reply Brief in Support of its Motion for Summary Judgment of No Invalidity Based on Medrad's Grounds for Filing the Reissue Application that Resulted in the '602 Reissue Patent, submitted on 06/13/05			
	AE	Medrad's Memorandum in Reply to Tyco's Memorandum in Opposition to Medrad's Motion for Summary Judgment of No Invalidity Based on the Saini Article and the 1987 Magnetic Resonance Injector Operation Manual, submitted on 06/13/05 (Filed Under Seal)			
	AF	Medrad's Memorandum in Reply to Tyco's Memorandum in Opposition to Medrad's Motion for Summary Judgment of No Invalidity of Claims 9, 33, and 38 under 35 U.S.C. § 102 Based on Medrad's EM-1 Prototype Injector, submitted on 06/13/05 (Filed Under Seal)			
	AG	Medrad, Inc.'s Pretrial Statement, submitted on 08/09/05 (Confidential Portions Redacted)			
	AH	Revised Supplemental Rebuttal Expert Report of Bruce Rosen, submitted on 08/19/05 (Confidential Pursuant to Protective Order Attorney's Eyes Only), and exhibit thereto, including Exhibit 1, Declaration of Joseph B. Havrilla, dated May 26, 2005 and Exhibit A thereto, Medrad, Inc. January 10, 1991 letter to John Allen of ETL Testing Laboratory.			
	AI	Defendants' Motion in Limine Seeking Determination That Certain Printed Publications Are Prior Art by Tyco Healthcare Group LP, Mallinckrodt Inc., Liebel-Flarsheim Co., Nemoto Kyorindo Co., Ltd., submitted on 08/25/05			
	AJ	Defendants' Notice Under 35 U.S.C. § 282, submitted on 09/02/05			

Examiner Signature		Date Considered	
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				Application Number	09/545,582
				Filing Date	April 7, 2000
				First Named Inventor	Arthur E Uber III
				Art Unit	3737
				Examiner Name	Ruth Smith
Sheet	4	of	6	Attorney Docket Number	23578-0010

NON PATENT LITERATURE DOCUMENTS					
	AK	Defendants' Pretrial Statement, submitted on 09/09/05 (Confidential Portions Redacted)			
	AL	Medrad, Inc.'s Opposition to Defendants' Motion in Limine Seeking Determination that Certain Printed Publications are Prior Art, submitted on 10/11/05			
	AM	Respondents', Liebel-Flarsheim Company, Inc.'s Mallinckrodt Inc.'s (NY) and Mallinckrodt Inc.'s (Del.) Responses to Complainant Medrad's First Set of Interrogatories (Nos. 1-23), Response to Interrogatory No. 14 at pages 15-20, submitted at the United States International Trade Commission, In the Matter of Certain Magnetic Resonance Injection Systems and Components Thereof, June 19, 2000.			
	AN	Respondents', Liebel-Flarsheim Company, Inc.'s Mallinckrodt Inc.'s (NY) and Mallinckrodt Inc.'s (Del.) Responses to Complainant Medrad's First Set of Interrogatories (Nos. 24-57), Response to Interrogatory Nos. 40, 41, 43 and 45 at pages 20-29, submitted at the United States International Trade Commission, In the Matter of Certain Magnetic Resonance Injection Systems and Components Thereof, July 18, 2000.			
	AO	Medrad, Inc. Spectris MR Injector System, Volume 1 (MAL-PIT-013931-32); Medrad, Inc. Letter to FDA from J. Burtick dated November 23, 1993 (MAL-PIT-013933-35); Medrad, Inc. Attachment B – Device Descriptions for Medrad Spectris MR Injector and 65ml Qwik Fit Syringe (MAL-PIT-014133-37) (REDACTED); Attachment E – Bench Test Data (MAL-PIT-014223, MAL-PIT-014225) (REDACTED)			
	AP	Magnevist package insert – Injection, 1983 (MAL-PIT-000989)			
	AQ	Electronic Industries Standard, RS-422A (1990)			
	AR	MR Injector Electronic Hardware Requirements Spec Draft, Jon Manley, 9/9/93 (MRD007952-976) (Attorney's Eyes Only, Subject to Protective Order)			
	AS	Medrad, Inc. Hardware Requirements Specification (MD 108035-062) (Attorney's Eyes Only, Subject to Protective Order)			
	AT	Medrad, Inc. Product Specification MR Injector System (MRD041022-071) (Attorney's Eyes Only, Subject to Protective Order)			
	AU	Medrad, Inc. Memorandum from D. Zatezalo re. New OTR Design, dated September 1, 1993 (MRD028119-122) (Attorney's Eyes Only, Subject to Protective Order)			

Examiner Signature		Date Considered
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				Art Unit	3737
				Examiner Name	Ruth Smith
Sheet	5	of	6	Attorney Docket Number	23578-0010

NON PATENT LITERATURE DOCUMENTS					
	AV	Medrad, Inc. Spectris MR Injector System, Volume 1 of Initial Submission, Table of Contents (MRD036094-95) (Attorney's Eyes Only, Subject to Protective Order); Medrad, Inc. Letter to FDA from J. Burtick dated November 23, 1993 (MRD36096-98) (Attorney's Eyes Only, Subject to Protective Order); Medrad, Inc. Attachment B – Device Descriptions for Medrad Spectris MR Injector and 65ml Qwik Fit Syringe (MRD036292-97) (Attorney's Eyes Only, Subject to Protective Order); Attachment E – Bench Test Data (MRD036464-74) (Confidential Subject to Protective Order)			
	AW	Battery Life Testing document signed by J. Manley, March 4, 1993 (MD 108094-95) (Attorney's Eyes Only, Subject to Protective Order)			
	AX	Medrad, Inc. MR Injector Motor Box Wiring Diagram, No. 90122D05004, August 31, 1990 (MRD034099) (Attorney's Eyes Only Subject to Protective Order)			
	AY	"Pre-Filled MR Cartridge Agreement Medrad/Squibb Diagnostics," effective November 18, 1992, and Amendment #1 thereto (Confidential Subject to Protective Order)			

**The Following Documents Include Confidential Information Pursuant to Protective Order and Have Not Been Submitted:**

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the articles (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
N/A	AZ	Report of Robert Lee, Ph.D., Under Rule 26(a)(2)(B) of the Federal Rules of Civil Procedure, filed on behalf of Tyco Healthcare Group LP <i>et al.</i> , submitted on 05/16/03 (Portions of This Report Include Information that has been Designated Attorneys' Eyes Only Under the Protective Order), and exhibits thereto, including Exhibit B, various pages from an Alpha Wire Company document, dated 3/8/00.			
N/A	BA	Report of Tyco expert Robert A. Bell, Ph.D., filed on behalf of Tyco Healthcare Group LP <i>et al.</i> , submitted on 05/20/03 (Portions of This Report Include Information that has been Designated Attorneys' Eyes Only Under the Protective Order)			
N/A	BB	Expert Report of Robert A. Bell, M.D., filed on behalf of Tyco Healthcare Group LP <i>et al.</i> , submitted on 02/14/05 (Portions of This Report Include Information that has been Designated Attorneys' Eyes Only Under the Protective Order)			
N/A	BC	Defendants' Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 112, ¶ 1, submitted on 04/25/05 (Filed Under Seal)			

Examiner Signature		Date Considered
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				Examiner Name	Ruth Smith
Sheet	6	of	6	Attorney Docket Number	23578-0010

**The Following Documents Include Confidential Information Pursuant to Protective Order and Have Not Been Submitted (Cont.):**

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the articles (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
N/A	BD	Defendants' Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 103, submitted on 04/25/05 (Filed Under Seal)			
N/A	BE	Defendants' Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 102(b) for being "On Sale", submitted on 04/25/05 (Filed Under Seal)			
N/A	BF	Defendants' Memorandum in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. RE. 37,602 Based on Prior Public Use, submitted on 04/25/05 (Filed Under Seal)			
N/A	BG	Defendants' Memorandum in Opposition to Medrad's Motion for Summary Judgment of No Invalidity Based on the Saini Article and the 1987 Magnetic Resonance Injector Operation Manual, submitted on 05/27/05 (Filed Under Seal)			
N/A	BH	Defendants' Memorandum in Opposition to Medrad's Motion for Summary Judgment of No Invalidity of Claims 9, 33, and 38 under 35 U.S.C. § 102 Based on Medrad's EM-1 Prototype Injector, submitted on 05/27/05 (Filed Under Seal)			
N/A	BI	Defendants' Reply in Support of Their Motion for Summary Judgment of Invalidity of U.S. Patent No. RE 37,602 Based on Prior Public Use, submitted on 06/13/05 (Filed Under Seal)			
N/A	BJ	Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 112, ¶ 1, submitted on 06/13/05 (Filed Under Seal)			
N/A	BK	Defendants' Reply Memorandum of Their Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 102(b) for being "On Sale", submitted on 06/13/05 (Filed Under Seal)			
N/A	BL	Defendants' Reply in Support of Their Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. RE. 37,602 Under 35 U.S.C. § 103, submitted on 06/13/05 (Filed Under Seal)			
N/A	BM	The 50 <sup>th</sup> Annual Scientific Congress of Japanese Society of Radiology, Notes pp. 1-4, 04/6-9/1994, MR Contrast Medir Injector trial manufacture (Nemoto-003159-163) (Confidential – Subject to Protective Order Attorneys' Eyes Only)			

Examiner Signature		Date Considered	
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